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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,817	09/14/1998	DANIEL CAPUT	IVD924	6529

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/077,817

Applicant(s)
Caput et al

Examiner
Nirmal S. Basi

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 28, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-36, 38, and 44-59 is/are pending in the application.
- 4a) Of the above, claim(s) 5-36, 38, and 52-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☒ The proposed drawing correction filed on Jun 25, 2001 is: a) ☒ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☒ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Art Unit: 1646

DETAILED ACTION

1. Amendments filed 9/28/01 (paper number 24) and 6/25/01 (paper number 22) have been entered. Applicant has canceled claims 1-4, 37 and 39-43 and added new claims 44-59. The Abstract provided by Applicant, in paper number 24, is approved and has been entered. The partial duplicate half page 46 has been canceled.

2. Applicant's election with traverse of Group I (Claims 1-4, 37 and 39-43 drawn to a polypeptide comprising SEQ ID NO:2), in Paper No. 24, is acknowledged. Applicant has canceled claims 1-4, 37 and 39-43 and added new claims 44-59. The traversal is on the ground(s) that the claims drawn to different aspects of a common inventive concept and should be examined together. This is not found persuasive because the inventions are distinct for reasons of record (paper number 17, 8/31/00) and a search of groups I-IX would not be co-extensive particularly with regard to the literature search. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Newly added claims 44-51, directed to the elected invention of Group I, see paper number 17, will be examined with elected Group I. Since applicant has received an action on the merits for the originally presented invention (Group I), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, new claims 52-59, directed to methods of treatment and screening, and original claims 5-36 and 38, are withdrawn

Art Unit: 1646

from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 9/28/01 have been approved. Formal Drawings are required.

The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is

Art Unit: 1646

determined to be unacceptable by the Office, applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

4. The rejection under 35 USC § 101 and 35 USC § 112, 1st paragraph as pertaining to the claimed invention not being supported by either a specific and substantial asserted utility or a well established utility is withdrawn in view of Applicants arguments and Amendments filed in paper number 22.

5. The rejection of original claim 37 (pharmaceutical composition) under under 35 U.S.C. 112, first paragraph is maintained as it would apply to new claims 48-51 (pharmaceutical composition). Applicant argues that the claimed polypeptides are useful in blocking the activity of IL-13. Applicant further states, "As noted by Applicants, Il-13 is a mediator of inflammatory mechanisms (p. 4, lines 15-160, and as confirmed in the research publication by Will-Karp et al". Applicants arguments have been fully considered but not found persuasive. The reference of Will-Karp et al is post filing art and the concept of "blockade of IL-13 was effective in reversing allergen-induced asthma" is not disclosed in instant application and can not be used to support for a pharmaceutical composition. Further although the polypeptide of claimed invention has been stated in the specification as useful for blocking the activity of Il-13, IL-13 being a mediator of inflammatory mechanism, this does form a nexus to treatment of a specific disease. The

Art Unit: 1646

following rejection under 35 U.S.C. 112, first paragraph of newly added claims 48-51 is essentially the same as that applied to claims 37 and 42 in paper number 19, (12/19/00), and is applied to new claims 48-51.

Claims 48-51 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 48-51 are rejected based on the failure of the specification to enable one of skill in the art to make and/or use the pharmaceutical composition encompassed by the claim. The pharmaceutical composition comprising the polypeptide set forth in SEQ ID NO:2, comprising residues 1-343 or 1-337 of SEQ ID NO:2 and comprising SEQ ID NO:12 (the 8 c-terminal residues of SEQ ID NO:2 are substituted by the 6 residues of SEQ ID NO:11) infer a drug or medication with therapeutic activity. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim without undue experimentation. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (8 USPQ2d 1400 (CA FC 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented. The term "pharmaceutical" implies a treatment of a disease. Neither the specification nor the prior art provide sufficient guidance as to what specific diseases could be treated by administering a "pharmaceutical composition" comprising

Art Unit: 1646

the claimed. Attempting to identify a disease treatable by such a "pharmaceutical composition" would constitute undue experimentation. Therefore one of skill in art would have to identify a disease treatable by said "pharmaceutical composition", determine effective compositions, determine effective doses to achieve the intended purpose, determine routes of effective administration, determine if the "pharmaceutical composition" can reach its target tissue without degradation and determine if it has a therapeutic effect, all of which would constitute undue experimentation. Therefore, the unpredictability to achieve all the afore mentioned goals and the lack of guidance provided in the specification, the disclosure fails to enable one of skill in the art how to make and/or use the "pharmaceutical composition" encompassed by the claims 48-51. Amending the claims to a composition instead of "pharmaceutical composition would overcome Examiners rejection.

6. Applicant has not addressed the rejection of claims 1, 4, 37, 39-43, in paper number 19, as it would apply to newly added claims, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The aforementioned rejection is applied to new claims 44, 47, 48, and 51 and is essentially the same as that applied to original claims 1, 4, 37, 39-43, and is stated below.

Claims 44, 47, 48, and 51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

Art Unit: 1646

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

The claims are drawn to isolated polypeptide comprising

- a) polypeptide comprising residues 1-343 or 1-337 of SEQ ID NO:2
- b) pharmaceutical composition comprising a)

Instant disclosure, nor prior art provide any data or suggest that the products ii) and iii) have any biological activity. The instant disclosure of the distinct polypeptide of SEQ ID NO: ((380 amino acids) does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, fusion polypeptides and variants thereof; and pharmaceutical compositions comprising said polypeptides. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed or which sequences may be biologically active and what is that biological activity. There is no description of the sites at which variability may be tolerated and there is no information

Art Unit: 1646

regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and predict their use in c) and d) above. Further no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the regulatory regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the full length, truncated, fusion polypeptides and variants thereof. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, the disclosure of the ability to have any biological active sequence derived from SEQ ID NO:2, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

An adequate written description of a protein, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of a protein is more than a mere statement that it is part of the invention and reference to a potential method for

Art Unit: 1646

isolating it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description of the invention of claims 44, 47, 48, and 51.

6. Applicant states, "the purified polypeptides here-claimed are neither taught nor suggested by the prior art, in particular the Sigma Catalog and Vita et al", cited by the Examiner.

Applicants arguments have been fully considered and found persuasive in part. The rejection of Sigma Catalog is withdrawn in view of Applicants cancellation of claim 1. The rejection of Vita et al, under 35 U.S.C. 102(b), is maintained as it would apply to new claims 44, 45 and 47.

Applicant has not provide any arguments as to why the polypeptide of Vita does not anticipate the polypeptide comprising SEQ ID NO:2. The following rejection under 35 U.S.C. 102(b) of newly added claims 44, 45 and 47 is essentially the same as that applied to claims 1 and 2 in paper number 19, (12/19/00), and is applied to address the new claims.

*** Applicant cannot rely upon the foreign priority papers(FRANCE 95/14424) to overcome Claim Rejections - 35 USC § 102 because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

Art Unit: 1646

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6a. Claims 44, 45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Vita et al. (reference B on PTO form 1449).

Claims 44, 45 and 47 are drawn to a purified polypeptide comprising an amino acid sequence of SEQ ID NO:2.

Vita et al. discloses IL-13 β receptor polypeptide purified from solubilized cells by electrophoresis (see for example Fig 4, panel B). Vita et al. do not disclose the sequence of said polypeptide, however, absent evidence to the contrary, it would be expected that the purified polypeptide disclosed by Vita et al. would inherently comprise the amino acid sequence of the polypeptide set forth in SEQ ID NO:2, comprising residues 1-343 or 1-337 of SEQ ID NO:2. This is evidenced by the fact that the polypeptide disclosed by Vita et al. possesses the same activity as the instant SEQ ID NO:2, with respect to IL-13 crosslinking, is from the same organism as the instantly claimed polypeptide (human), and has an apparent molecule weight comparable to that disclosed in the instant specification (approximately 70kD).

The claims are further anticipated by Collins et al.

6b. Claims 44, 45 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins et al. (Reference A).

Art Unit: 1646

Claims 44, 45 and 47 are drawn to a purified polypeptide comprising an amino acid sequence of SEQ ID NO:2, comprising residues 1-343 or 1-337 of SEQ ID NO:2.

Collins discloses a polypeptide, SEQ ID NO:4, which is 100% identical to SEQ ID NO:2, see attached sequence comparison attached, thereby anticipating claims 44, 45 and 47, absent evidence to the contrary.

No claim is allowed

Advisory Information

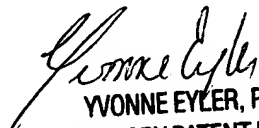
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
December 16, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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